

OECA and Regional Report

Week Ending February 1, 2019

**** Enforcement Confidential Items are Highlighted in Red ****

Index:

[TOC \o "1-3" \n \h \z \u] _____

[PAGE]

Non-Responsive

Non-Responsive

[PAGE]

Non-Responsive

Non-Responsive

[PAGE]

Region 3

Regular Highlights:

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

Non-Responsive

Non-Responsive

Region 5 signs a Consent Agreement and Final Order with Kremers Urban Pharmaceuticals Inc., Resolving Clean Air Act Violations

On December 31, 2018, the U.S. Environmental Protection Agency, Region 5 filed a Consent Agreement and Final Order (CAFO) with the Regional Hearing Clerk that simultaneously commences and concludes an action against Kremers Urban Pharmaceuticals Inc., (Kremers) under Section 113(d) of the Clean Air Act (the Act), 42 U.S.C. § 7413(d). Kremers owns and operates a pharmaceutical manufacturing facility in Seymour, Indiana (Facility). The Facility has approximately 770 employees and operates on a 24/7 batch-process operation. The Facility manufactures liquid, capsule, and tablet forms of specialty generic pharmaceutical drugs. During the encapsulation process, Kremers uses solvents that contain hazardous air pollutants (HAPs) for its pharmaceutical manufacturing operations, and therefore it is subject to the requirements of the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production (Subpart GGG).

On June 29, 2017, EPA issued to Kremers a Finding of Violation (FOV) alleging that it violated Subpart GGG. On January 25, 2018, EPA issued a guidance memorandum withdrawing EPA's "once in always in" policy for the classification of major sources of HAPs under Section 112 of the Clean Air Act. With the new guidance, sources of HAPs previously classified as "major sources" may be reclassified as "area" sources at any time so long as the facility limits its potential to emit below major source thresholds.

Since Kremers was no longer a "major source" of HAP, Kremers is reclassifying as an "area" source under the NESHAP for Chemical Manufacturing Area Sources at 40 C.F.R. Part 63, Subpart VVVVVV (Subpart VVVVVV). In an administrative order on consent issued on December 26, 2018, Kremers will comply with Subpart VVVVVV and ensure that it can maintain and demonstrate compliance with the applicable synthetic minor limit by

[PAGE]

incorporating requirements and measures necessary to ensure compliance into a federally-enforceable permit.

Under the terms of the CAFO, Kremers will pay \$60,000 for the CAA violations. Kremers will also perform a supplemental environmental project (SEP) designed to protect families by abating lead-based paint hazards in a number of child-occupied facilities or residential properties near the Facility at a cost of \$225,000. The State of Indiana has been notified about this settlement and does not object. (Contacts: Albana Bega, Air and Radiation Division, 312-353-4789, and Mary McAuliffe, Office of Regional Counsel, at 312-886-6237.

Non-Responsive

Region 6

Regular Highlights:

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

[PAGE]

Non-Responsive

Non-Responsive

[PAGE]